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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,444

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Anthony Pantages

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4902

57360 7590 04/17/2007

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/786,444

Applicant(s)

PANTAGES ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10 and 12-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10 and 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 30 January 2007. The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 3, 5, 7-10, and 12-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al., or **Green** (U.S. Patent No. **5,674,231**) in view of Martinez et al., or **Martinez** (U.S. Patent No. **5,593,412**).

Claims 1, 17, 19, 20, and 22: Green discloses a method for delivering a closure element **102** in a blood vessel **104**, the closure element being carried by a carrier assembly **42** slidable on an outer surface of an elongate member **30**, the elongate member comprising and at least partially overlying the carrier assembly, the elongate member being provided with a locator member **60** slidably associated therewith, the locator member having one or more expandable positioning elements **62**, **64** on its distal portion, the method comprising inserting the distal end of the elongate member into an opening through tissue, advancing the locator member distally from the distal end of the elongate member, expanding the one or more positioning elements, withdrawing the locator member until the positioning elements contact tissue, advancing

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the carrier assembly towards the distal end of the elongate member, and deploying the closure element from the carrier assembly within the opening to substantially seal the opening (Figures 1-4, 7, 10-11 and col. 5, lines 45-67, col. 6, lines 1-8, col. 7, lines 18-67, col. 8, lines 1-52). Green discloses the claimed invention except for a skin, or sleeve member, overlying at least a portion of the outer surface between the carrier assembly and a distal end of the elongate member and a the carrier assembly causing the skin to separate from the outer surface of the elongate member as the carrier assembly is advanced towards the distal end.

Martinez teaches a skin, or sleeve, **18** overlying at least a portion of the outer surface between the carrier assembly and a distal end of the elongate member and the carrier assembly causing the skin to separate from the outer surface of the elongate member as the carrier assembly is advanced towards the distal end (Figures 1-5 and col. 4, lines 53-67 and col. 5, lines 1-2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a skin, as taught by Martinez, to Green since it was known in the art that skins or sheaths are commonly used in deployment devices to protect delivery devices and are often opened or removed in order to unveil the delivery device.

Claim 2: Green discloses removing the elongate member from the opening (col. 8, lines 44-52).

Claims 3 and 5: Green discloses the claimed invention except for the skin comprising a weakened region extending towards the distal end of the elongate member, the weakened region tearing as the carrier assembly is advanced towards the distal end of

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the elongate member, and the skin expanding to a cross-section that is larger than a cross-section of the elongate member as the carrier assembly is advanced towards the distal end.

Martinez teaches a skin comprising a weakened region extending towards the distal end of the elongate member, the weakened region tearing as the carrier assembly is advanced towards the distal end of the elongate member, and the skin expanding to a cross-section that is larger than a cross-section of the elongate member as the carrier assembly is advanced towards the distal end (Figures 1-5 and col. 4, lines 53-67 and col. 5, lines 1-2). It would have been obvious to one of ordinary skill in the art to provide a skin with a weakened region, as taught by Martinez, to Green since it was known in the art that skins or sheaths are commonly used in deployment devices to protect delivery devices with weakened regions to serve as a simple opening mechanism that does not require a second instrument or mechanism.

Claim 7: Green discloses the claimed invention except for the skin comprising an outer surface that is substantially slippery for facilitating advancement of the elongate member into the opening through tissue.

Martinez teaches the skin comprising an outer surface that is substantially slippery for facilitating advancement of the elongate member into the opening through tissue and that it allows for retraction of the sheath and allows for expansion for the element onto which it is disposed (col. 3, lines 30-42 and col. 4, lines 53-67 and col. 5, lines 1-2). It would have been obvious to one of ordinary skill to provide a skin with a slippery outer surface, as taught by Martinez, to Green since it was known in the art that

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a lubricated, slippery surfaces allow for facilitated translational movement and also in order to allow for expansion of the elongate member or the element onto which it is disposed.

Claim 8: Green and Martinez disclose the claimed invention except for the opening through tissue extending through one or more layers of fascia, and wherein the skin facilitates advancement of the carrier assembly through the one or more layers of fascia. It would have been obvious to one of ordinary skill in the art for the skin to facilitate advancement of the carrier assembly through one or more layers of fascia, or connective tissues of the blood vessel, in Green and Martinez, since it was known in the art that sheaths and skins protect as well as facilitate advancement of deployment devices through layers of tissue in the surgical site.

Claim 9: Green discloses the opening through tissue communicating with a blood vessel, and wherein the deploying step comprises substantially sealing the opening from blood flow therethrough with the closure element. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claim 10: Green discloses coupling the carrier assembly to a proximal end of the elongate member. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claims 12-13: Green discloses the claimed invention except for the skin comprising a plurality of longitudinal slots, the slots opening as the carrier assembly is advanced, thereby expanding the skin, and the slots being staggered relative to one another such that the skin assumes a zigzag mesh configuration as it expands.

Martinez teaches a skin comprising a plurality of longitudinal slots, the slots opening as the carrier assembly is advanced, thereby expanding the skin, and the slots being staggered relative to one another such that the skin assumes a zigzag mesh configuration as it expands (Figures 1-5 and col. 4, lines 53-67 and col. 5, lines 1-2). It would have been obvious to one of ordinary skill in the art to provide a skin having a plurality of slots assuming a zigzag mesh configuration, as taught by Martinez, to Green since it was known in the art that this configuration allows for more flexibility and lateral, axial, and longitudinal expansion.

Claim 14: Green discloses contracting said positioning elements and withdrawing said locator member. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claim 15: Green discloses the distal end of the elongate member being inserted into the lumen of a blood vessel and wherein the positioning elements of the locator member are expanded within the lumen of a blood vessel. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claim 16: Green discloses the step of withdrawing the locator member causes the positioning elements to come into contact with the wall of the blood vessel. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claims 18 and 21: Green and Martinez disclose the claimed invention except for the blood vessel being the femoral artery. It would have been obvious to one of ordinary skill to provide the blood vessel as being a femoral artery in Green and Martinez, since it was known in the art that the femoral artery is a blood vessel and that the vascular hole closure device and method may be applied to any blood vessel.

3. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Green** (U.S. Patent No. **5,674,231**) and **Martinez** (U.S. Patent No. **5,593,412**), as applied to Claim 1 above, and further in view of Kanner et al., or **Kanner** (U.S. Patent No. **5,868,755**).

Claim 6: Green and Martinez disclose the claimed invention except for the skin being bonded to the outer surface of the elongate member by an adhesive and wherein the adhesive has sufficient adhesive strength such that the skin is peeled away from the outer surface as the carrier assembly is advanced towards the distal end.

Kanner teaches a skin **1** being bonded to the outer surface of the elongate member by an adhesive and wherein the adhesive has sufficient adhesive strength such that the skin is peeled away from the outer surface as the carrier assembly is advanced towards the distal end (col. 4, lines 1-16). It would have been obvious to one of ordinary skill in the art to provide a skin bonded to the outer surface to the elongate member, as taught by Kanner, to Green and Martinez, since it was known in the art to provide adhesives that provide temporary security and to avoid undesired movement of the sheath.

Response to Arguments

4. Applicant's arguments filed 30 January 2007 have been fully considered but they are not persuasive.

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5. Applicant generally argues that Green et al. and Martinez et al. are not within the same field of endeavor since Green et al. is directed to an occlusion device and Martinez et al. is directed to a dilation device, which teach away from each other. The examiner disagrees. The present invention is a method which is directed to deploying a closure element, as does the invention of Green et al. Although the teaching of Martinez et al. is directed towards the use of a dilating or stent device, it is more importantly a *delivery or deployment method*, and therefore involves the advancement of a device through a body lumen and is within the same field of endeavor as the present invention and Green et al. For that reason, one skilled in the art would look to modify the "conventional cannula" of Green et al. with the deployment sheath of Martinez et al. that "separates from the outer surface of the elongate member as the carrier assembly is advanced towards the distal end," as maintained above in Martinez et al., in order to effectively protect and subsequently unveil the device being delivered without additional manipulation by a secondary instrument or mechanism.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "M J Hayes", is written in a cursive style.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER